 K061283

510(k) Summary of Safety and Effectiveness Information

The following information is furnished in accordance with 21 CFR 807.92(a):

1. ***Submitter's name and address***:
Micro Medical Limited
Quayside
Chatham Maritime
Chatham
Kent
ME4 4QY
United Kingdom

DEC 1 4 2006

Postal Box Address
Micro Medical Ltd, PO Box 6, Rochester, Kent. ME1 2AZ. UK

2. ***Submitter's telephone number and fax number:***
Tel: 011 44 1634 893500
Fax: 011 44 1634 893600

3. ***Contact person:***
Mr. Glen Hillsley - Regulatory Affairs Manager

4. ***Trade/proprietary name of the device:***
Pulmolife (Catalogue No. PL10)

5. ***Classification name and number of the device:***
Diagnostic Spirometer, 21CFR 868.1840

6. ***Legally marketed predicate devices to which substantial equivalence is claimed:***

Micro Medical Ltd. Micro Spirometer, Model No. MS01/3. Ref. 510(k) No. K963035, approved by FDA on November 1, 1996.

8. *Description of the device that is the subject of this premarket notification:*

The PulmoLife is a battery operated hand held portable spirometer. It uses a uni-directional, rotating vane, flow sensing turbine to measure lung function parameters, specifically Forced Expiratory Volume in the 1st second of expiration (FEV1) and FEV1 as a percentage of the predicted value (FEV1 %predicted). Lung age estimation is also given. It is supplied with one way valve safety mouthpieces, carrying pouch and instruction manual.

9. *Intended use and indication for use:*

The device measures the exhaled breath of a patient, specifically FEV1. The results can be used for the diagnosis of COPD in adult smokers.

10. *Targeted Population*

Adult patients of either gender requiring lung function evaluations, particularly smokers for the early detection of Chronic Obstructive Pulmonary Disease (COPD)

11. *Environment of Use*

Places where a qualified clinician desires to take lung function measurement such as in hospitals, clinics, physicians' offices, laboratories.

12. *Technological characteristics:*

The design, packaging, and other technological characteristics of the Micro Medical PulmoLife device are considered to be substantially equivalent to those of the predicate devices.

This concludes the 510(k) summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Glen Hillsley
Regulatory Affairs Manager
Micro Medical, Limited
Quayside
Chatham Maritime
Chatham, Kent,
ME4 4QY
UNITED KINGDOM

DEC 14 2006

Re: K061283
Trade/Device Name: PulmoLife
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: December 1, 2006
Received: December 8, 2006

Dear Mr. Hillsley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):
Unknown – not yet assigned by FDA K061283

Device Name:
PulmoLife

Indications For Use:
The device measures expiratory lung function parameters, specifically FEV1 and conforms to ATS standards for diagnostic devices. The results obtained can be used for screening of COPD in adult smokers.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

General Hospital
Devices
K061283